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WASHINGTON, D.C. 20231

Case Docket No.: 526/20

Transmitted herewith for filing is the patent application of

Inventors: UZI ESHEL AND JACOB LAZAROVITZ

For : INTERNAL CATHETER

Enclosed are:

- ☒ 2 sheets of informal drawings.
- ☒ An assignment of the invention to ARGOMED LTD.
- ☐ A certified copy of a _____ application.
- ☐ An associate power of attorney.
- ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27.
- ☐ Other - _____

The filing fee has been calculated as shown below:

	(Col.1) NO. FILED	(Col.2) NO. EXTRA
FOR:		
BASIC FEE		
TOTAL CLAIMS	11-20=	0
INDEP CLAIMS	2 - 3=	0
.X. Recordal of Assignment		

SMALL ENTITY	
RATE	FEE
	\$ 395
0x11=	\$ 0
0x41=	\$ 0
	\$ 40
TOTAL	\$ 435

OR
OR
OR
OR
OR
OR

OTHER THAN A SMALL ENTITY	
RATE	FEE
	\$ 790
x22=	\$
x82=	\$
=	\$
TOTAL	\$

If the difference in Col.1 is less than zero, enter "0" in Col.2

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- ☐ A check in the amount of \$ _____ to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 06-2140. A duplicate copy of this sheet is enclosed.
 - ☒ Any additional filing fees required under 37 CFR 1.16.
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- ☒ The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to Deposit Account No. 06-2140. A duplicate copy of this sheet is enclosed.
 - ☒ Any patent application processing fees under 37 CFR 1.17.
 - ☐ The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of allowance, pursuant to 37 CFR 1.311(b).
 - ☒ Any filing fees under 37 CFR 1.16 for presentation of extra claims.

Respectfully,

Mark M. Friedman
Reg. No. 33,883

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APPLICATION FOR PATENT

Inventors: UZI ESHEL AND JACOB LAZAROVITZ

Title: INTERNAL CATHETER

FIELD AND BACKGROUND OF THE INVENTION

5 The present invention relates to an internal catheter for insertion into the urethra of a patient and, more particularly to a catheter specifically adapted for treating obstruction of the prostatic urethra. Such a catheter may be used for drainage of fluids and tissue particles through the patient's prostatic urethra following a non-surgical medical procedure
10 such as thermal treatment of the prostate, wherein a long-term indwelling catheter is needed.

Benign prostate hyperplasia (BPH) is currently treated by using surgical procedures such as trans urethral resection of the prostate (TURP) or non-surgical procedures such as thermal treatment of the prostate.
15 Temporary blockage of the prostatic urethra usually takes place following such treatments due to extensive swelling and edema formation.

Various attempts have been made to provide internal catheters or stents for insertion into the patient's prostatic urethra for enabling effective drainage of fluids and tissue particles therethrough.

20 Examples of such internal catheters and stents are disclosed in U.S. Pat. Nos. 3,811,450; 5,176,626; and 5,514,178.

However, none of the prior art devices provides an internal catheter having first and second cylindrical members interconnected by means of a tube, the tube for inflating a balloon located at the end of the catheter, the balloon for appropriately locating the catheter at the prostatic urethra.

5 Further, none of the prior art devices provide a guiding element including an inflatable balloon for introducing the catheter to the patient's urethra.

SUMMARY OF THE INVENTION

According to the present invention there is provided a catheter for
10 insertion into a patient's urethra, comprising: (a) first and second tubular members having such a diameter for enabling drainage of physiological fluids therethrough, each of the first and second tubular members having a wall of a specific thickness, the first and second tubular members being interconnected by means of a connecting tube of substantially smaller
15 diameter; (b) an inflatable balloon attached to the second tubular member, the inflatable balloon being in fluid communication with the connecting tube. The inflatable balloon is for insertion to the patient's urinary bladder, the balloon for locating the second tubular member substantially within the patient's prostatic urethra such that the connecting tube is held by the
20 patient's sphincter.

Preferably, the connecting tube extends through the walls of the first and second tubular members.

The wall of the second tubular member may include a chamber in fluid communication with the connecting tube and the inflatable balloon.

Preferably, the connecting tube extends beyond the first tubular member so as to enable the connection thereof to an external inflating
5 element.

According to further features in preferred embodiments of the invention described below, the catheter further includes a guiding element, including: (a) a substantially elongated tubular member having a hollow, the elongated tubular member having a closed end for insertion through the
10 patient's urethra and an open end for connection to an external inflating element; (b) an inflatable balloon attached to the elongated tubular member, the inflatable balloon being in fluid communication with the hollow of the tubular member. The guiding element is for insertion through the first and second tubular members of the catheter so as to
15 inflate the inflatable balloon of the guiding element against the walls thereof, thereby effectively fixing the catheter to the guiding element. Preferably, the inflatable balloon of the guiding element is substantially elongated and thin in cross section.

20 BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1a is a schematic longitudinal section of an internal catheter according to the present invention, wherein the locating balloon is inflated.

FIG. 1b is a schematic longitudinal section of an internal catheter according to the present invention, wherein the locating balloon is
5 deflated;

FIG. 2 is a cross sectional view taken along line A-A in FIG. 1b;

FIG. 3 is a schematic longitudinal section of a guiding element according to the present invention;

FIG. 4 is a schematic longitudinal section of the guiding element
10 illustrated in FIG. 3 while received within the internal catheter, wherein the locating balloon is inflated;

FIG. 5 is a cross sectional view taken along line B-B in FIG. 4; and

FIG. 6 is a schematic longitudinal section of the guiding element
illustrated in FIG. 3 while received within the internal catheter, wherein
15 the locating balloon is deflated.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an internal catheter for introduction into a patient's obstructed prostatic urethra so as to enable effective drainage of fluids and tissue particles through the obstructed urethra.

The principles and operation of apparatus and method according to the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, Figures 1a, 1b and 2 illustrate an internal catheter according to the present invention. As shown, internal catheter 1 includes first and second tubular members, 2 and 4, interconnected by means of a connecting tube 6, the connecting tube for inflating a balloon 20 attached to tubular member 4.

As shown in the figures, connecting tube 6 preferably extends through the entire length of walls 8 of tubular member 2 and through a portion of the length of wall 10 of tubular member 4, such that the proximal end 6a of connecting tube 6 is embedded within wall 10 and the distal end 6b of connecting tube 6 is connected to an external connector 18.

Connector 18 is connectable to an injector for injecting fluid into connecting tube 6 so as to inflate balloon 20. Connector 18 preferably includes a valve or a tap (not shown) for controlling the flow of fluid into and out of connecting tube 6.

Wall 10 of tubular member 4 preferably includes a chamber 13 in fluid communication with connecting tube 6. An aperture 14 located on wall 10 provides fluid communication between chamber 13 and balloon 20.

Balloon 20 is preferably attached to the external surface of wall 10 and encloses a segment thereof.

When the catheter is introduced to the patient's urethra, balloon 20 is inserted to the patient's urinary bladder in a deflated form. Balloon 20 is then inflated so as to temporarily anchor the catheter at a required position such that the portion 4a of tubular member 4 is located at the prostatic urethra, segment 6c of tubular connection 6 which connects tubular members 2 and 4 is held by the patient's sphincter, tubular member 2 is located at the patient's urethra distally to the sphincter, and the portion 6d of tubular connection 6 extends through the length of the patient's urethra. Connector 18 is located externally to the patient body.

As shown in the figures, tubular members 2 and 4 are preferably circular in cross section and feature substantially circular openings 15a, 15b, 16a and 16b, for allowing effective drainage of fluids and tissue particles. Alternatively, tubular members 2 and 4 may be cut at an angle so that openings 15a and 15b feature a substantially elliptical shape.

Referring now to FIG. 3, according to the present invention there is provided a guiding element 3 for introducing catheter 1 to the patient's body. As shown in the figure, guiding element 3 preferably includes an elongated tubular member 30 having a proximal end 32 for insertion to the patient's urethra and a distal end 33 for connection to an external connector 39. Proximal end 32 preferably features a rounded shape for

facilitating the insertion of the catheter through the patient's urethra. Distal end 33 is preferably open and circular in cross section for allowing connecting thereof to connector 39. Tubular member 30 is preferably made of a semi-rigid material.

5 Attached to tubular member 30 is an inflatable balloon 38, the balloon being in fluid communication with the hollow 34 of tubular member 38 via apertures 36 located along the length of wall 35 of tubular member 30. Preferably, inflatable balloon 38 is attached to the external surface of wall 35 and encloses a substantial portion of tubular member 30. The length of balloon 38 preferably substantially equals the distance 10 between opening 16a of tubular member 4 and opening 15b of tubular member 2. Balloon 38 may extend along a limited portion of tubular member 30. Preferably, balloon 38 is substantially thin in cross section.

Connector 39 is connectable to an injector for injecting fluid into 15 the hollow 34 of tubular member 30. Connector 39 preferably includes a valve or a tap (not shown) for controlling the flow of fluid into and out of hollow 34 of tubular member 30.

FIGs. 4-6 illustrates the usage of a guiding element according to the present invention for the introduction of catheter 1 to the patient's body.

20 Referring to FIG. 6, guiding element 3 is inserted into tubular members 2 and 4 while balloon 38 of guiding element 3 is deflated. Balloon 38 is then inflated by injecting fluid such as water or air into

tubular member 30 by means of an injector connected to connector 39 (not shown) so as to substantially engage balloon 38 with the walls 8 and 10 of tubular members 2 and 4. Balloon 38 is inflated to such an extent so as to press the walls of balloon 38 against walls 8 and 10, thereby substantially
5 fixing tubular members 2 and 4 to the balloon.

The assembly shown in FIG. 6 is then inserted into the patient's urethra so as to locate balloon 20 of catheter 3 within the patient's urinary bladder. Balloon 20 is then inflated by injecting fluid into connecting tube 6 by means of an injector connected to connector 18 (not shown) so as to
10 temporarily anchor balloon 20 within the patient's urinary bladder, thereby appropriately positioning portion 4a of tubular member 4 within the patient's prostatic urethra such that portion 6c of connecting tube 6 is held by the patient's sphincter.

Following the positioning of the internal catheter within the patient's
15 urethra, balloon 38 of guiding element 3 is deflated by pumping the fluid out of the balloon and tubular member 30 by means of the injector connected to connector 39. Guiding element 3 is then extracted from within the catheter and removed from the patient's body.

The positioning of tubular member 2 at one side of the sphincter
20 and tubular member 4 at the other side of the sphincter effectively anchors the catheter in place. Therefore, balloon 20 may be only used as a locating balloon rather than a permanent anchoring balloon. Accordingly, following

the extraction of guiding element 3 balloon 20 is preferably deflated by pumping the fluid out of the balloon by means of the injector connected to connector 18.

Portion 6d of connecting tube 6 may then be cut so as to hide the
5 end of the connecting tube within the patient's urethra, thereby minimizing the risk of contamination and providing maximal comfort to the patient. Alternatively, portion 6d of connecting tube 6 may be cut so as to remain externally to the body, thereby enabling facile extraction of the catheter.

Alternatively, the step of using an injector for deflating balloon 20
10 is omitted and balloon 20 is deflated by cutting portion 6d of connecting tube 6.

While the invention has been described with respect to a limited
number of embodiments, it will be appreciated that many variations,
15 modifications and other applications of the invention may be made.

WHAT IS CLAIMED IS:

1. A catheter for insertion into a patient's urethra, comprising:
 - (a) first and second tubular members having such a diameter for enabling drainage of physiological fluids therethrough, each of said first and second tubular members having a wall of a specific thickness, said first and second tubular members being interconnected by means of a connecting tube of substantially smaller diameter;
 - (b) an inflatable balloon attached to said second tubular member, said inflatable balloon being in fluid communication with said connecting tube,

said inflatable balloon for insertion to the patient's urinary bladder, said balloon for locating said second tubular member substantially within the patient's prostatic urethra such that said connecting tube is held by the patient's sphincter.

2. The catheter of claim 1, wherein said connecting tube extends through said walls of said first and second tubular members.

3. The catheter of claim 1, wherein said wall of said second tubular member includes a chamber in fluid communication with said connecting tube and said inflatable balloon.

4. The catheter of claim 1, wherein said connecting tube extends beyond said first tubular member so as to enable the connection thereof to an external inflating element.

5. The catheter of claim 1, further including a guiding element, said guiding element including:

- (a) a substantially elongated tubular member having a hollow, said elongated tubular member having a closed end for insertion through the patient's urethra and an open end for connection to an external inflating element;
- (b) an inflatable balloon attached to said elongated tubular member, said inflatable balloon being in fluid communication with said hollow of said tubular member,

said guiding element for insertion through said first and second tubular members so as to inflate said inflatable balloon of said guiding element against said walls, thereby fixing said catheter to said guiding element.

7. The catheter of claim 1, wherein said inflatable balloon of said guiding element is substantially elongated.

8. The catheter of claim 1, wherein said inflatable balloon of said guiding element is substantially thin in cross section.

9. a guiding element for inserting a catheter into a patient's urethra, comprising:

- (a) a substantially elongated tubular member having a hollow, said elongated tubular member having a closed end for insertion through the patient's urethra and an open end for connection to an external inflating element;
- (b) an inflatable balloon attached to said elongated tubular member, said inflatable balloon being in fluid communication with said hollow of said tubular member,

said guiding element for insertion through the catheter so as to inflate said inflatable balloon of said guiding element against the catheter, thereby fixing the catheter to said guiding element.

10. The guiding element of claim 9, wherein said inflatable balloon is substantially elongated.

ABSTRACT OF THE DISCLOSURE

A catheter for insertion into a patient's urethra is provided, comprising: (a) first and second tubular members having such a diameter for enabling drainage of physiological fluids therethrough, the first and second tubular members being interconnected by means of a connecting tube of substantially smaller diameter; (b) an inflatable balloon attached to the second tubular member, the inflatable balloon being in fluid communication with the connecting tube. The inflatable balloon is inserted to the patient's urinary bladder so as to locate the second tubular member substantially within the patient's prostatic urethra such that the connecting tube is held by the patient's sphincter. Further according to the present invention there is provided a guiding element for insertion through the catheter, including: (a) a substantially elongated tubular member having a hollow, the elongated tubular member having a closed end for insertion through the patient's urethra and an open end for connection to an external inflating element; (b) an inflatable balloon attached to the elongated tubular member, the inflatable balloon being in fluid communication with the hollow of the tubular element, the inflatable balloon for inflation against the catheter so as to effectively fix the guiding element to the catheter.

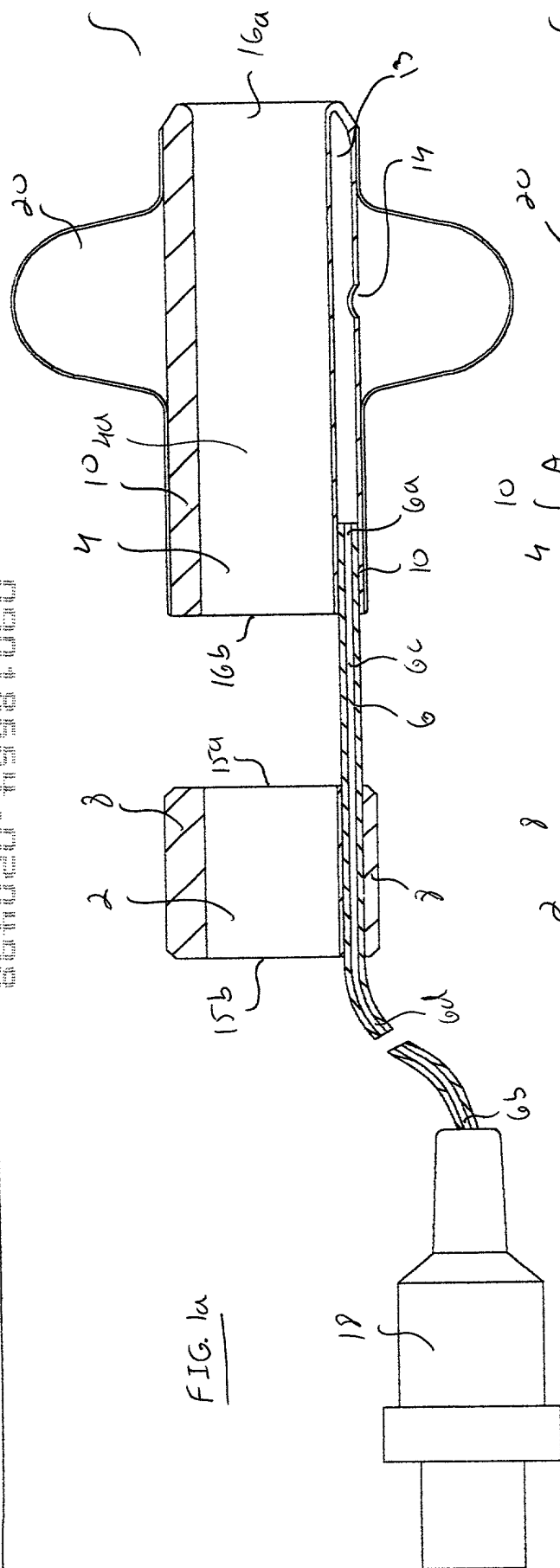


FIG. 1a

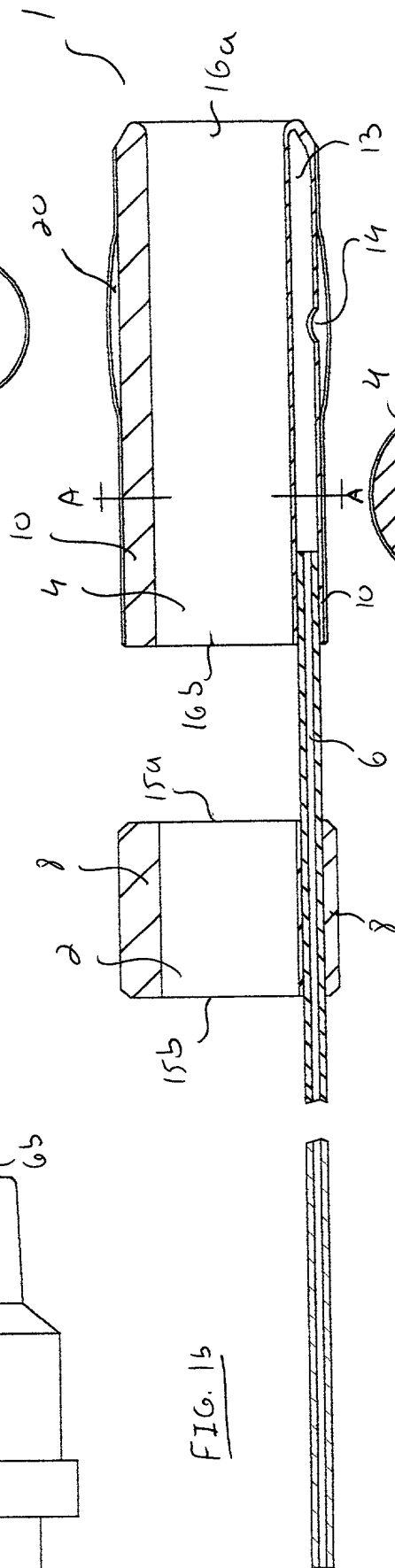


FIG. 15

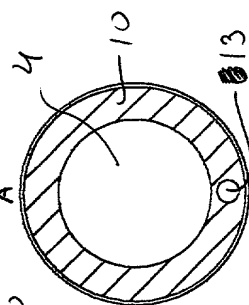


FIG. 2

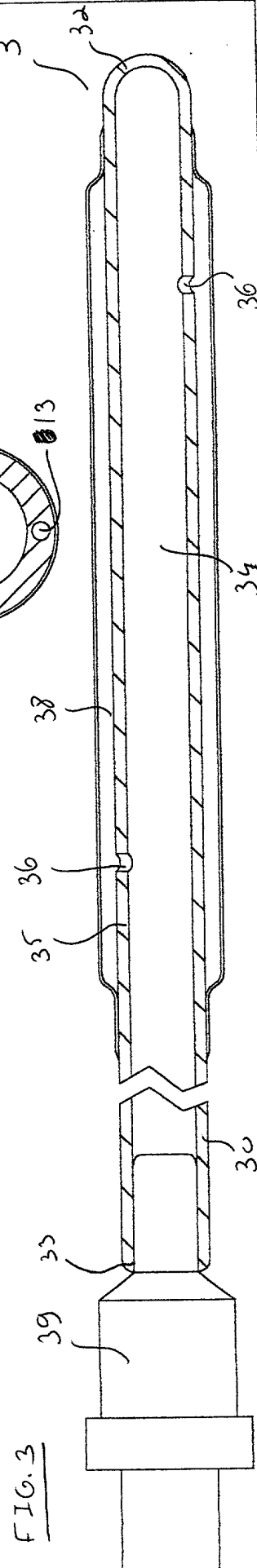
FIG. 3

FIG. 5

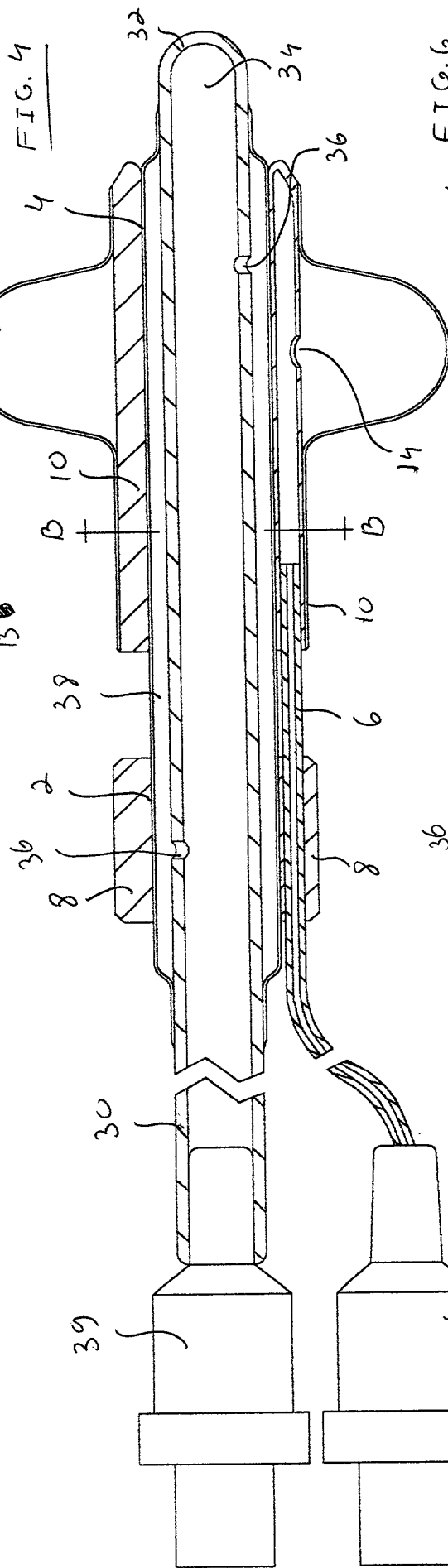
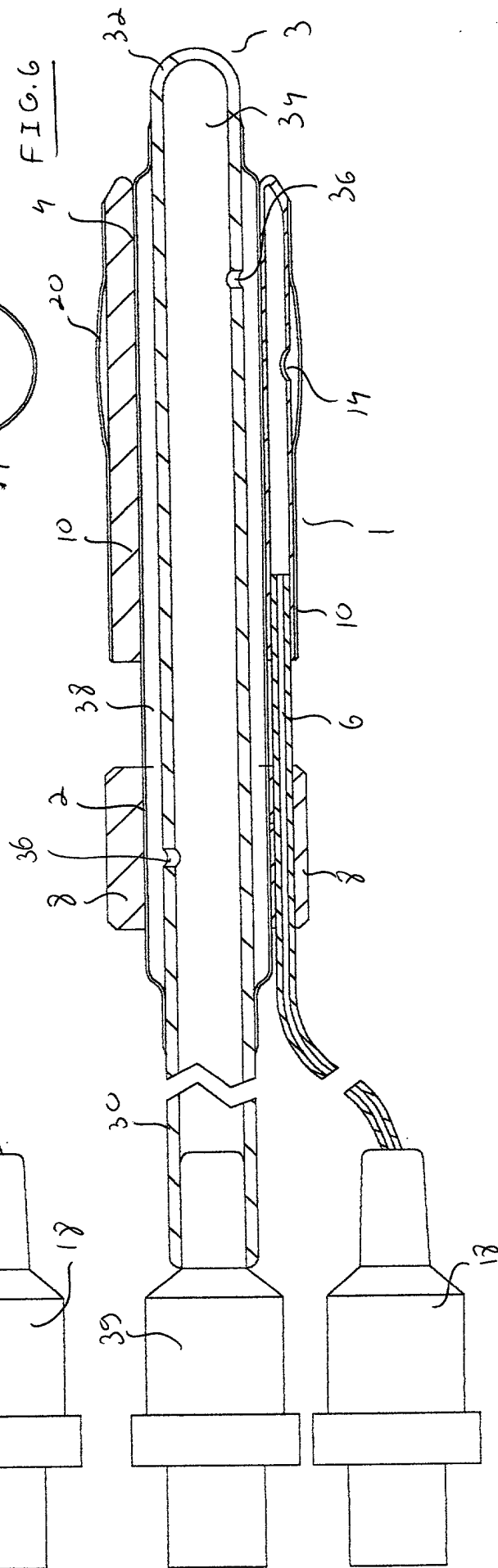


FIG. 6



Attorney Docket: 526/20

Combined Declaration For Patent Application and Power of Attorney

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;
 I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled INTERNAL CATHETER, the specification of which (check one) X is attached hereto.

_____ was filed on _____ as Application Serial No. _____ and was amended on _____
 I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
NONE (number)	(Country)	(Day, Month, Year Filed)	Yes	No
(number)	(Country)	(Day, Month, Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

NONE (Application Serial No.)	(Filing Date)	Status (patented, pending, abandoned)
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I hereby appoint the following attorneys, with full power of substitution, association, and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Mark M. Friedman Registration No. 33,883

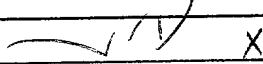
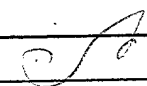
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Direct all telephone calls & faxes to:

ROBERT SHEINBEIN
 Phone (703) 415-1581
 Fax (703) 415-4864

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application of any patent issued thereon.

*FULL NAME OF SOLE OR FIRST INVENTOR UZI ESHEL	INVENTOR'S SIGNATURE 	DATE JAN 29, 1998
RESIDENCE 28 ACHI DAKAR, HERZELIA, ISRAEL	CITIZENSHIP ISRAELI	
POST OFFICE ADDRESS 28 ACHI DAKAR, HERZELIA, ISRAEL		
*FULL NAME OF SECOND INVENTOR JACOB LAZAROVITZ	INVENTOR'S SIGNATURE 	DATE JAN 24, 1998
RESIDENCE 87 JABOTINSKI, HOD HASHARON, ISRAEL	CITIZENSHIP ISRAELI	
POST OFFICE ADDRESS 87 JABOTINSKI, HOD HASHARON, ISRAEL		
*FULL NAME OF THIRD INVENTOR	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

SMALL BUSINESS CONCERN - NEW APPLICATION

Attorney Docket No.: 526/20IN THE UNITED STATES PATENT AND TRADEMARK OFFICEIn RE Application of: UZI ESHEL AND JACOB LAZAROVITZ

Filed Concurrently Herewith

For: INTERNAL CATHETERVERIFIED STATEMENT UNDER 37 CFR 1.27
CLAIMING STATUS AS A SMALL ENTITY

To The Commissioner of Patents and Trademarks:

I hereby declare that:

I am the owner of, or an official empowered to act on behalf of, the small business concern identified below:

Name of Concern: ARGOMED LTD.Address : 60 MEDINAT HAYEHUDIM, 46766 HERZELIA PITUACH, ISRAEL

The small business concern identified above, together with its affiliates, employs fewer than 500 persons and qualifies as a small business concern as defined in 37 CFR 1.9(d) for purposes of paying reduced fees under 35 USC § 41(a) and § 41(b) to the Patent and Trademark Office with regard to the above-entitled invention described in the specification filed herewith.

Rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above entitled invention.

If the rights held by the small business concern are not exclusive, each other party having rights to the invention is listed below, and no rights to the invention are held by any party who could not qualify as a small entity under 37 CFR 1.9(f), namely any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Full Name (Party 1): NONE

Address : _____

Status : ☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Full Name (Party 2): _____

Address : _____

Status : ☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty under 37 CFR 1.28(b) to file, in this application, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the issue fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing thereon.

UZI ESHEL
Name of Person SigningX [Signature]
SignatureX JAN 29, 1998
DateCapacity of Person Signing: PRESIDENTAddress of Person Signing : 28 ACHI DAKAR, HERZELIA, ISRAEL

INDEPENDENT INVENTOR - NEW APPLICATION

Attorney Docket No.: 526/20IN THE UNITED STATES PATENT AND TRADEMARK OFFICEIn RE Application of: UZI ESHEL AND JACOB LAZAROVITZ

Filed Concurrently Herewith

For: INTERNAL CATHETERVERIFIED STATEMENT UNDER 37 CFR 1.27
CLAIMING STATUS AS A SMALL ENTITY

To The Commissioner of Patents and Trademarks:

As a below named Inventor, I hereby declare that:

I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under 35 USC § 41(a) and § 41(b) to the Patent and Trademark Office with regard to the above-entitled invention described in the specification filed herewith.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any party who could not qualify as a small entity under 37 CFR 1.9(f), namely any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each party, if any, who could qualify as a small entity under 37 CFR 1.9(f) and to whom I have assigned, granted, conveyed or licensed or am under an obligation under contract or law to assign, grant, convey or license, any rights in the invention is listed below:

Full Name (Party 1): ARGOMED LTD.Address : 60 MEDINAT HAYEHUDIM, 46766 HERZELIA PITUACH, ISRAELStatus : ☐ Individual ☒ Small Business ☐ Nonprofit
Concern Organization

I acknowledge the duty under 37 CFR 1.28(b) to file, in this application, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the issue fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing thereon.

UZI ESHEL
Name of Inventor 1JACOB LAZAROVITZ
Name of Inventor 2_____
Name of Inventor 3X [Signature]
Signature of InventorX [Signature]
Signature of Inventor_____
Signature of InventorX Date: JAN 29, 1998